



## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[CMS-1445-N]

Medicare Program; Public Meeting Regarding Inherent Reasonableness of Medicare Fee Schedule Amounts for Non-Mail Order (Retail) Diabetic Testing Supplies

**ACTION:** Notice of meeting.

**SUMMARY:** This notice announces a public meeting that provides an opportunity for CMS to consult with representatives of suppliers and other interested parties regarding options to adjust the Medicare payment amounts for non-mail order diabetic testing supplies. This meeting will provide the public an opportunity to offer oral and written comments.

**DATES:** Meeting Date: The public meeting will be held on Monday, July 23, 2012, 9 a.m. to 1 p.m. eastern daylight time (e.d.t.).

Deadline for Attendees that are Foreign Nationals (reside outside the U.S.) Registration:

Prospective attendees that are foreign nationals (as described in section V. of this notice) are required to identify themselves as such, and provide the necessary information for security clearance (as described in section V. of this notice) by 5 p.m. e.d.t.

Thursday, July 5, 2012.

Deadline for All Other Attendees: All other individuals who plan to attend the public meeting must register by 5 p.m. e.d.t. Monday, July 16, 2012.

Deadline for Requesting Special Accommodations: Persons attending the meeting who are hearing or visually impaired, or have a condition that requires special assistance or

accommodations, are asked to contact the persons as specified in the **FOR FURTHER INFORMATION CONTACT** section of this notice no later July 9, 2012, 5 p.m., e.d.t.

Deadline for Submission of Written Comments: Written comments must be received at the address specified in the **ADDRESSES** section of this notice by 5 p.m. e.d.t., Monday, July 30, 2012. Once submitted, all comments are final.

**ADDRESSES:** Meeting Location: The public meeting will be held in the main auditorium of the central building of the Centers for Medicare and Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

Submission of Written Comments: Written comments may either be emailed to DMEPOS@cms.hhs.gov or sent via regular mail to Elliot Klein, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Mail Stop C5–03–17, Baltimore, MD 21244–1850.

Registration and Special Accommodations: Individuals wishing to participate or who need special accommodations or both must register by completing the on-line registration located at <http://www.cms.gov/apps/events/upcomingevents.asp> or by contacting one of the persons listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice.

**FOR FURTHER INFORMATION CONTACT:**

Hafsa Vahora at (410) 786–7899 or [Hafsa.Vahora@cms.hhs.gov](mailto:Hafsa.Vahora@cms.hhs.gov)

Elliot Klein at (410)786–0415 or [Elliot.Klein@cms.hhs.gov](mailto:Elliot.Klein@cms.hhs.gov)

**SUPPLEMENTARY INFORMATION:****I. Background****A. Process for Using Inherent Reasonableness Authority**

In the December 13, 2005 **Federal Register** (70 FR 73623), we published a final rule entitled "Medicare Program; Application of Inherent Reasonableness Payment Policy to Medicare Part B Services (Other Than Physician Services)" that finalized a process for establishing a realistic and equitable payment amount for Medicare Part B services (other than physicians' services) when the existing payment amounts are inherently unreasonable because they are either grossly excessive or grossly deficient. In that December 2005 final rule, we define grossly excessive and deficient payment amounts and provide the criteria for using valid and reliable data in making an inherent reasonableness determination.

Sections 1842(b)(8) and (9) of the Act and our regulations at 42 CFR 405.502(g) and (h) set forth the steps that the Secretary must follow in determining whether a payment amount is grossly excessive and in setting a special payment limit. Those steps are as follows:

- **Factors Considered In Determining Whether Payment Amount is Grossly Excessive or Deficient.** When making a determination that a payment amount is grossly excessive, we take into account several factors. Factors that may result in grossly excessive or deficient payment amounts include, but are not limited, to the following:

- ++ The marketplace is not competitive.

- ++ Medicare and Medicaid are the sole or primary sources of payment for a category of items and services.

++ The payment amounts for a category of items and services do not reflect changing technology, increased facility with that technology, or changes in acquisition, production, or supplier costs.

++ The payment amounts for a category of items or services in a particular locality are grossly high or lower than payment amounts in other comparable localities for the category of items or services.

++ Payment amounts for a category of items and services are grossly higher or lower than acquisition or production costs for the category of items and services.

++ There have been increases in payment amounts for a category of items or services that cannot be explained by inflation or technology.

++ The payment amounts for an item or service are grossly higher or lower than the payment amounts made for the item or service by other purchasers in the same locality.

++ A new technology exists which is not reflected in the existing payment allowances.

• Factors Considered in Establishing a Payment Limit. In establishing a payment limit for a category of items or services, we consider the available information that is relevant to the category of items or services and establish a payment amount that is realistic and equitable. The factors we consider in setting a payment include, but are not limited to the following:

++ Price markup.

++ Differences in charges.

++ Costs.

++ Use.

++ Payment amounts in other localities.

- Use of Valid and Reliable Data. In determining whether a payment amount is grossly excessive or deficient and in establishing an appropriate payment amount, we use valid and reliable data. To ensure that valid and reliable data are used, we must meet the criteria set forth at 42 CFR 405.502(g)(4)(i) through (xi), to the extent applicable.

- Impact Analysis. We consider the potential impact of the payment adjustments on quality, access, beneficiary liability, assignment rates, and participation of suppliers.

- Supplier Consultation. Before making a determination that a payment amount is not inherently reasonable, we consult with representatives of the supplier industry likely to be affected by the change in payment amounts.

- Publication of Proposed Determination. We publish a proposed notice in the **Federal Register** that--

- ++ Provides the proposed payment amount or method proposed to be established with respect to the item or service;

- ++ Explains the factors and data considered in determining that the payment amount was grossly excessive or deficient;

- ++ Explains the factors and data considered in determining the payment amounts or methodology, including the economic justification for a uniform fee or payment limit if it is proposed;

- ++ Explains the potential impact of the payment adjustments and;

- ++ Allows at least 60 days for public comment.

- Publication of Final Determination. We publish a final notice in the **Federal**

**Register** containing our final determination with respect to the payment amount to be established for the item or service, explaining the factors and data considered in making the final determination, and responding to public comments.

B. Mandate to Phase In Competitive Bidding Programs for Diabetic Testing Supplies

Sections 1847(a)(1)(A) and (a)(2)(A) of the Act mandate the implementation of competitive bidding programs for durable medical equipment (DME) and medical supplies, including diabetic testing supplies. Under these programs, contracts are to be awarded to suppliers for furnishing DME and medical supplies throughout the United States at reduced payment amounts. Diabetic testing supplies are supplies necessary for the effective use of durable blood glucose monitors and include test strips, lancets, spring-powered lancet devices, calibration solution/chips, and replacement batteries. In 2011, annual Medicare Part B allowed charges for these items were approximately \$1.6 billion, of which approximately \$552 million (over one-third) was attributed to claims for non-mail order items.

Section 1847(a)(1)(B)(ii) of the Act provides authority for phasing in items and services under the competitive bidding programs, starting with the highest cost and highest volume items and services or those items and services determined to have the largest savings potential. The majority of Medicare beneficiaries receive their diabetic testing supplies on a mail order basis, and the competitive bidding program was phased in first for supplies furnished via this delivery method as part of the Round One Rebid of the competitive bidding program. In 2011, Medicare-allowed payment amounts for a box of 50 mail order test strips were reduced by 55 percent on average in 9 local metropolitan areas as a result of these programs.

**TABLE 1: COMPARISON OF 2011 FEE SCHEDULE AMOUNTS (NON-MAIL ORDER AND MAIL ORDER) AND MAIL ORDER COMPETITIVE BIDDING AMOUNTS**

<b>Local Competitive Bidding Area</b>	<b>Fee Schedule Amount (Non-mail)</b>	<b>Fee Schedule Amount (Mail)</b>	<b>Competitive Bidding Amount</b>
Charlotte-Gastonia-Concord, NC-SC	\$34.85	\$30.03	\$14.50
Cincinnati-Middletown, OH	\$38.74	\$33.39	\$15.22
Cleveland-Elyria-Mentor, OH	\$38.74	\$33.39	\$15.62
Dallas-Fort Worth-Arlington, TX	\$36.24	\$31.24	\$14.25
Kansas City, MO-KS	\$34.35	\$29.60	\$13.94
Miami-Fort Lauderdale-Pompano Beach, FL	\$38.75	\$33.40	\$15.20
Orlando, FL	\$38.75	\$33.40	\$14.50
Pittsburgh, PA	\$38.75	\$33.40	\$14.50
Riverside-San Bernardino-Ontario, CA	\$38.75	\$33.40	\$13.88
Average of Nine Areas	\$37.55	\$32.36	\$14.62
National Average	\$37.67	\$32.47	

A national DMEPOS competitive bidding program for mail order diabetic testing supplies is scheduled to take effect in 2013. For this competition, and future competitions for diabetic testing supplies, the definitions of mail order item and non-mail order item set forth in 42 CFR 414.402 will be used to determine what items will be included in the competitions. These definitions are as follows:

- Mail Order Item-- Any item shipped or delivered to the beneficiary's home, regardless of the method of delivery.
- Non-Mail Order Item-- Any item that a beneficiary or caregiver picks up in person at a local pharmacy or supplier storefront.

Because annual allowed charges for non-mail order diabetic testing supplies are approximately \$552 million, this category of items and services represents the highest volume category of items or services yet to be phased in under the DMEPOS competitive bidding programs. Also, based on the results of the competition for mail order diabetic

testing supplies in nine Competitive Bidding Areas (CBAs) and a review of other pricing information for diabetic testing supplies in general, we believe the savings potential for non-mail order diabetic testing supplies is significant. Although we recognize that there are pricing differences between mail order and non-mail order diabetic testing supplies because of the delivery methods for these supplies, information about the prices of mail order diabetic testing supplies can inform the analysis of prices for non-mail order diabetic testing supplies because several key cost components are identical for both, such as product acquisition costs and administrative costs, including claims processing and paperwork costs. In addition to the significant program and beneficiary savings that can be generated by lowering the payment amounts for non-mail order diabetic testing supplies, adjusting the payment amounts for these items to bring them more in line with the allowed payment amounts for mail order diabetic testing supplies is important for a number of reasons, including the fact that maintaining a significant discrepancy between what Medicare pays for mail order supplies versus non-mail order supplies may encourage fraud and abuse such as billing for mail order supplies as if they were furnished on a non-mail order basis. The discrepancy also penalizes beneficiaries who choose to obtain their supplies on a non-mail order basis in the form of significantly higher coinsurance payments.

#### C. Use of Inherent Reasonableness Authority to Delay Phase in of Items Under Competitive Bidding

Rather than phasing in non-mail order diabetic testing supplies under the competitive bidding program at this time, we are considering an alternative for adjusting the payment amounts for non-mail order diabetic testing supplies in the short term using



information obtained from the local Round One Rebid competitions for mail order supplies and other pricing information to establish special payment limits for non-mail order diabetic testing supplies. We believe that this alternative would allow beneficiaries the greatest degree of choice in deciding where to obtain their non-mail order diabetic testing supplies as suppliers would not have to be awarded contracts to continue furnishing these items to Medicare beneficiaries. It also has the potential to reduce the significant discrepancy in payment amounts between mail order and non-mail order diabetic testing supplies and generate beneficiary and program savings sooner than could be achieved through competitive bidding. National reductions to the fee schedule amounts would reduce the savings potential that could result from application of competitive bidding. This would alter the standing of non-mail order diabetic testing supplies relative to other items in terms of level of priority for phase-in under the competitive bidding program. It is also possible that use of the inherent reasonableness authority over time to establish special payment limits for non-mail order diabetic testing supplies could mean that including these items under the competitive bidding program will not be necessary as significant savings would not be achieved.

Because information generated from the local Round One Rebid competitions for mail order diabetic testing supplies and information about the cost of diabetic testing supplies is available, we believe we have the information necessary to determine whether payment amounts for non-mail order diabetic testing supplies are grossly excessive and should be adjusted using our inherent reasonableness authority. Use of the inherent reasonableness authority would delay or eliminate the need to have local pharmacies compete and win contracts in order to continue furnishing non-mail order diabetic testing

supplies to Medicare beneficiaries, thereby maintaining the option of obtaining these items from any local, enrolled Medicare supplier. Again, given the high volume of expenditures for these items, competitive bidding for these items would need to be implemented in the near future if the savings potential for these items is not lowered through use of the inherent reasonableness authority.

## **II. Meeting Agenda**

The tentative agenda is as follows:

- Sign In
- Opening Remarks
- CMS Presentation Regarding Payment for Non-Mail Order Diabetic Testing

### **Supplies**

- ++ Mandate for Competitive Bidding
- ++ Establishing Special Payment Limits as a Means of Delaying Competitive

### **Bidding for these Items**

- ++ Steps of the Inherent Reasonableness Process
- Public Comments
- Closing Remarks

## **III. Meeting Registration**

### **A. Required Information for Registration**

The following information must be provided when registering:

- Name.
- Company name and address.
- Direct-dial telephone and fax numbers.

- E-mail address.
- Special needs information.

A CMS staff member will confirm your registration by e-mail.

#### B. Registration Process

All comments will be heard and accepted after the presentation by CMS staff is completed until the end of the public meeting. If there are comments after the meeting, we will accept written comments until the date specified in the **DATES** section of this notice.

#### C. Additional Meeting/Registration Information

This public meeting is scheduled in order to fulfill the requirement of section 1842(b)(9)(A) of the Act to consult with representatives of suppliers or other individuals who furnish an item or service before making a determination under section 1842(b)(8)(B) of the Act with regard to that item or service.

### **IV. Comment Format**

#### A. Oral Comments From Meeting Attendees

Oral comments will be heard from the meeting attendees during the allotted time during the public meeting. Comments should last no longer than 10 minutes each to allow as much opportunity for comments from as many interested individuals as possible. There will be a sign up during the meeting to accommodate oral comments and speakers will be called in the order in which they sign up. We encourage anyone providing oral comments to also submit their comments in writing.

#### B. Written Comments From Meeting Attendees

Written comments will be accepted from the general public and meeting

registrants until the date specified in the **DATES** section. Comments must be sent to the address specified in the **ADDRESSES** section of this notice. Meeting attendees may also submit their written comments at the meeting.

#### C. Summary Comments and Responses From Public Meeting

The summarized comments and responses from the public meeting will be provided in the proposed notice for the adjustment of fee-schedule amounts for non-mail order diabetic testing supplies.

#### **V. Security, Building, and Parking Guidelines**

The meeting is held within the CMS Complex which is not open to the general public. Visitors to the complex are required to show a valid U.S. Government issued photo identification, preferably a driver's license, at the time of entry. Participants will also be subject to a vehicular search before access to the complex is granted. Participants not in possession of a valid identification or who are in possession of prohibited items will be denied access to the complex. Prohibited items on Federal Property include but are not limited to, alcoholic beverages, illegal narcotics, dogs or other animals except Seeing Eye dogs and other dogs trained to assist the handicapped, explosives, firearms or other dangerous weapons (including pocket knives).

Once cleared for entry to the complex participants will be directed to parking by a security officer. In order to ensure expedited entry into the building it is recommended that participants have their ID and a copy of their written meeting registration confirmation readily available and that they do not bring laptops or large/bulky items into the building. Participants are reminded that photography on the CMS complex is prohibited. CMS has also been declared a tobacco free campus and violators are subject

to legal action.

In planning arrival time, we recommend allowing additional time to clear security. Individuals who are not registered in advance will not be permitted to enter the building and will be unable to attend the meeting. The public may not enter the building earlier than 45 minutes before the convening of the meeting. Guest access to the complex is limited to the meeting area, the main lobby, and the cafeteria. If a visitor is found outside of those areas without proper escort they may be escorted out of the facility.

Also be mindful that there will be an opportunity for comment and we request that everyone waits for the appropriate time to present their opinions. Disruptive behavior will not be tolerated and may result in removal from the meetings and escort from the complex. No visitor is allowed to attach USB cables, thumb drives or any other equipment to any CMS information technology (IT) system or hardware for any purpose at anytime. Additionally, CMS staff is prohibited from taking such actions on behalf of a visitor or utilizing any removable media provided by a visitor.

We cannot assume responsibility for coordinating the receipt, transfer, transport, storage, set-up, safety, or timely arrival of any personal belongings or items used for demonstration or to support a comment. Special arrangements and approvals are required at least 2 weeks prior to the public meeting in order to bring pieces of equipment or medical devices. These arrangements need to be made with the public meeting coordinator. It is possible that certain requests made in advance of the public meeting could be denied because of unique safety, security or handling issues related to the equipment. A minimum of 2 weeks is required for approvals and security procedures.

Any request not submitted at least 2 weeks in advance of the public meeting will be denied.

CMS policy requires that every foreign visitor is assigned a host. The host/hosting official is required to inform the Division of Critical Infrastructure Protection (DCIP) at least 12 business days in advance of any visit by a foreign national visitor. Foreign National visitors will be required to produce a valid passport at the time of entry. Attendees that are Foreign Nationals need to identify themselves as such, and provide the following information for security clearance to the public meeting coordinator by the date specified in the **DATES** section of this notice:

- Visitor's full name (as it appears on passport).
- Gender.
- Country of origin and citizenship.
- Biographical data and related information.
- Date of birth.
- Place of birth.
- Passport number.
- Passport issue date.
- Passport expiration date.
- Dates of visits.
- Company name.
- Position/Title.

Meeting participants should arrive early to allow time to clear security and sign-in. The meeting is expected to begin promptly as scheduled.

**CMS-1445-N**

**Authority:** Section 1842(b)(9) of the Act.

**Dated:** June 19, 2012

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**Marilyn Tavenner,**  
Acting Administrator,  
Centers for Medicare & Medicaid Services.

**BILLING CODE 4120-01-P**

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